Nelson Labs
A Sotera Health company

Sponsor:

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	HSD-TYP2 LOT #191121
Purchase Order:	20191121
Study Number:	1244613-S01
Study Received Date:	25 Nov 2019
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~173 mm x ~153 mm
Positive Control Average:	1.7 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.3 µm

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Curtis Glover For

Study Director — Janelle R. Bentz, M.S.

06 Dec 2019

Study Completion Date

1244613-S01

Results:

Test Article Number	Percent BFE (%)
1	>99.9
2	99.9
3	99.7
4	99.8
5	99.8

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.0	29.3
2	3.1	30.2
3	2.9	28.5
4	3.0	29.0
5	3.0	29.2

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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Sponsor:

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	SAMPLE ID : HSD-TYP2 LOT #191121
Purchase Order:	20191121
Study Number:	1244612-S01
Study Received Date:	25 Nov 2019
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 201905892 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	2.4	62	3	65.0	27.1
2	2.5	3	3	6.1	2.5
3	2.5	17	3	20.1	8.1
4	2.5	9	6[a]	14.6	5.9
5	2.4	22[a]	3	25.0	10.4
Recovery Efficiency	87.4%				

< = No Organisms Detected
Note: The results are reported as colony forming units (CFU) per mask.
[a] Spreader. Count is considered a minimum estimate due to swarming of certain colonies on the membrane.

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Robert Putnam electronically approved — 16 Dec 2019 17:54 (+00:00)
Study Director Robert Putnam — Study Completion Date and Time

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	91%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Potato Dextrose Agar Tryptic Soy Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 - 7 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 5 - 7 days at 20-25°C, then enumerated.

DECLARATION OF CONFORMITY

We
Name and address of manufacturer:

declare on our own responsibility that
The medical device: 3 PLY Face Mask
Model# HSD-TYP2

Meets the provisions of Medical Device Directive (Council directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by directive 2007/47/EC) and related harmonized standards EN14683:2019 . We take full responsibility for all content in this declaration.

Classification: Classified as class I non sterile according to Annex IX, rule 1 of the Directive 93/42/EEC.

Conformity assessment procedure: Conformity assessment was performed according to Annex VII of the Directive 93/42/EEC.

The Authorized Representative within the EU who has been empowered to enter into commitments on our behalf is:
Lotus NL B.V.
Koningin Julianaplin 10, Ie Verd, 2595AA, The Hague, Netherlands.

2024-05-25
Validity period

2020-04-05 in
Place, date

Name:
Position: Director Manager